Listing of Claims

Please cancel claims 2, 43-56, 134-181 and 355-357 without prejudice. This listing of claims will replace all prior versions and listings of claims in the application.

1. (Previously Presented) A therapeutic device, comprising a device which locally administers radiation, and a spacer, wherein said spacer comprises a polymer and a cell-cycle inhibitor.

2. (Cancelled)

3. (Withdrawn) The device according to claim 1 wherein said device is a radioactive rod.

4. (Withdrawn) The device according to claim 1 wherein said device is a radioactive disk.

5. (Original) The device according to claim 1 wherein said device is a radioactive seed.

6. (Withdrawn) The device according to claim 1 wherein said device is a radioactive suture.

7. (Cancelled)

8. (Previously Presented) The device according to claim 1 wherein said cell-cycle inhibitor is released by said polymer.

9. (Original) The device according to claim 1 wherein said radiation is released from a polymer.

10. (Cancelled)

11. (Previously Presented) The device according to claim 1 or 9 wherein said polymer is a biodegradable polymer.

12. (Previously Presented) The device according to claim 1 wherein said polymer comprises poly (lactic acid).

13. (Withdrawn) The device according to claim 1 wherein said polymer comprises a copolymer of poly (caprolactone) and poly (lactic acid).

14. (Withdrawn) The device according to claim 1 wherein said polymer comprises MePEG.

15. (Previously Presented) The device according to claim 1 wherein said radiation is a radioactive source selected from the group consisting of I^{125}, Pd^{103}, Ir^{192}, Co^{60}, Cs^{137}, and Ru^{106}.

16. (Withdrawn) The device according to claim 1 wherein said cell-cycle inhibitor is a taxane.

17. (Withdrawn) The device according to claim 1 wherein said cell-cycle inhibitor is a topoisomerase inhibitor.

18. (Previously Presented) The device according to claim 1 wherein said cell-cycle inhibitor is an alkylating agent, anti-metabolite, or vinca alkaloid.

19. (Previously Presented) A therapeutic device, comprising:

a radioactive source sized to be positioned into the tissue of a patient adjacent to a site to be treated by locally administered radiation from the radioactive source; and

a spacer comprising a cell-cycle inhibitor positioned adjacent to the radioactive source.

20. (Original) The device according to claim 19 further including a carrier member supporting the radioactive source.

21. (Withdrawn) The device according to claim 20 wherein the carrier member is a suture.

22. (Withdrawn) The device according to claim 21 wherein the radioactive source is disposed within the suture.

23. (Withdrawn) The device according to claim 22 wherein the radioactive source comprises a plurality of radioactive seeds, and the seeds are positioned at locations along a length of the suture.

24. (Withdrawn) The device according to claim 21 wherein a cell-cycle inhibitor is positioned within the suture.

25. (Withdrawn) The device according to claim 21 wherein a cell-cycle inhibitor is positioned within the suture by being absorbed by the suture prior to positioning of the suture in the tissue.

26. (Withdrawn) The device according to claim 21 wherein a cell-cycle inhibitor is carried by a carrier material positioned one of within the suture or on an outer surface of the suture, and the carrier material is a material selected to release a cell-cycle inhibitor when the suture is within the tissue.

27. (Withdrawn) The device according to claim 26 wherein the material selected for the carrier material is a polymer.

28. (Withdrawn) The device according to claim 26 wherein a cell-cycle inhibitor is carried by the carrier material by being absorbed by the carrier material prior to positioning of the suture in the tissue.

29. (Withdrawn) The device according to claim 21 wherein a cell-cycle inhibitor is carried by a carrier material positioned within the suture or on an outer surface of the suture, and the carrier material is a material selected to elute a cell-cycle inhibitor when the suture is within the tissue.

30. (Withdrawn) The device according to claim 21 wherein the suture has at least a portion of the suture comprised of a material that carries a cell-cycle inhibitor.

31. (Withdrawn) The device according to claim 21 wherein a cell-cycle inhibitor is carried by the suture, and the suture is a material selected to release a cell-cycle inhibitor when the suture is within the tissue.

32. (Withdrawn) The device according to claim 31 wherein the material selected for the carrier member is a polymer.

33. (Withdrawn) The device according to claim 31 wherein a cell-cycle inhibitor is carried by the suture by being absorbed by the suture prior to positioning of the suture in the tissue.

34. (Withdrawn) The device according to claim 21 wherein a cell-cycle inhibitor is carried by the suture, and the suture is a material selected to elute a cell-cycle inhibitor when the suture is within the tissue.

35. (Withdrawn) The device according to claim 21 wherein a cell-cycle inhibitor is positioned on an outer surface of the suture prior to positioning of the suture in the tissue.

36. (Withdrawn) The device according to claim 21 wherein the suture has an outer member positioned at least partially about an outer surface of the suture prior to positioning of the suture in the tissue, and a cell-cycle inhibitor is carried by the outer member.

37. (Withdrawn) The device according to claim 36 wherein the outer member is a coating at least partially covering the outer surface of the suture.

38. (Withdrawn) The device according to claim 37 wherein the coating is a polymeric material and a cell-cycle inhibitor is within the polymeric material.

39. (Withdrawn) The device according to claim 37 wherein the outer member is a material selected to release a cell-cycle inhibitor when the suture is within the tissue.

40. (Withdrawn) The device according to claim 39 wherein the material selected for the outer member is a polymer.

41. (Withdrawn) The device according to claim 37 wherein the outer member is a material selected to elute a cell-cycle inhibitor when the suture is within the tissue.

42. (Withdrawn) The device according to claim 21 wherein a cell-cycle inhibitor is one of chemically linked to or coated on the radioactive suture.

43. – 56. (Cancelled)

57. (Original) The device according to claim 19 wherein the radioactive source comprises a plurality of radioactive seeds.

58. – 65. (Cancelled)

66. (Previously Presented) The device according to claim 19 wherein the spacer is a material selected to release a cell-cycle inhibitor when within the tissue.

67. (Original) The device according to claim 66 wherein the material selected for the spacer is a polymer.

68. (Previously Presented) The device according to claim 19 wherein a cell-cycle inhibitor is carried by the spacer by being absorbed by the spacer prior to positioning of the spacer in the tissue.

69. (Previously Presented) The device according to claim 19 wherein the spacer is a material selected to elute a cell-cycle inhibitor when within the tissue.

70. (Previously Presented) The device according to claim 19 wherein the spacer is a polymeric material and a cell-cycle inhibitor is within the polymeric material.

71. (Previously Presented) The device according to claim 19 wherein a cell-cycle inhibitor is positioned on an outer surface of the spacer.

72. (Original) The device according to claim 71 wherein a cell-cycle inhibitor is positioned on the outer surface of the spacer prior to positioning of the spacer in the tissue.

73. (Previously Presented) The device according to claim 19 wherein a cell-cycle inhibitor is carried by a carrier material positioned on an outer surface of the spacer, and the carrier material is a material selected to elute a cell-cycle inhibitor when the spacer is within the tissue.

74. (Original) The device according to claim 73 wherein a cell-cycle inhibitor is carried by the carrier material by being absorbed by the carrier material prior to positioning of the spacer in the tissue.

75. (Previously Presented) The device according to claim 57 wherein the spacers are positioned between the seeds and are sized to be received in a catheter for insertion into the tissue.

76. (Previously Presented) The device according to claim 19 wherein the spacers are elongated with a length and positioned with a lengthwise orientation extending between the adjacent seeds between which positioned, and the spacer length is selected to position and hold the seeds within the tissue in a desired spatial pattern based upon the radiation pattern desired to be administered to the site to be treated.

77. (Previously Presented) The device according to claim 57 including a spacer positioned between adjacent ones of the plurality of radioactive seeds, the spacers both holding the adjacent seeds spaced apart while in the tissue and holding the plurality of seeds together as part of a continuous thread while being positioned in the tissue.

78. (Original) The device according to claim 77 wherein the spacers are formed from a spacer material having a liquid phase and a solid phase, the spacers being formed using the spacer material in the liquid phase immediately prior to the time of positioning of the seeds into the tissue by placing the liquid phase spacer material between adjacent ones of the

seeds and then allowing the spacer material to change to the solid phase to form the continuous thread.

79. (Previously Presented) The device according to claim 57 including a spacer positioned between adjacent ones of the plurality of radioactive seeds, the spacers holding the adjacent seeds spaced apart while in the tissue, the spacers being a spacer material having a liquid phase and a solid phase, the spacers being formed using the spacer material in the liquid phase immediately prior to the time of positioning of the seeds into the tissue by placing the liquid phase spacer material between adjacent ones of the seeds and then allowing the spacer material to change to the solid phase prior to positioning of the spacers in the tissue.

80. (Original) The device according to claim 79 for use with a catheter, wherein the seeds are positioned in the catheter in spaced apart relation and the spacer material in the liquid phase is placed between adjacent ones of the seeds and then allowed to change to the solid phase, after changing to the solid phase and without removing the seeds and the spacers from the catheter, the seeds and the spacers being positioned in the catheter in a molded state ready for positioning in the tissue using the catheter.

81. (Original) The device according to claim 80 wherein after the spacer material has been allowed to change to the solid phase, the seeds and the spacers are in the form of a continuous thread holding the plurality of seeds together for positioning in the tissue and holding the adjacent seeds spaced apart while in the tissue.

82. (Original) The device according to claim 80 wherein the spacer material is in the liquid phase when heated to a liquid phase temperature above a body temperature of the patient, and in the solid phase when allowed to cool to a solid phase temperature below the liquid phase temperature.

83. (Previously Presented) The device according to claim 57 further comprising a cell-cycle inhibitor chemically linked to the seeds.

84. – 181. (Cancelled)

182. (Previously Presented) A method for treating cellular proliferation, comprising administering to a patient a therapeutic device according to any one of claims 1, 5, 12, 15, 16, and 57.

183. – 200. (Cancelled)

201. (Previously Presented) The method according to claim 182 wherein said cellular proliferation is due to cancer.

202. (Withdrawn) The method according to claim 182 wherein said cellular proliferation is due to stenosis or restenosis.

203. (Withdrawn) The method according to claim 182 wherein said cellular proliferation is due to an adhesion.

204. (Withdrawn) The method according to claim 182 wherein said cellular proliferation is due to vascular disease.

205. (Withdrawn) The method according to claim 182 wherein said cellular proliferation is due to arthritis.

206. (Withdrawn) The method according to claim 182 wherein said cell-cycle inhibitor or radioactive source is administered close to the surface of the body.

207. (Previously Presented) The method according to claim 182 wherein said cell-cycle inhibitor or radioactive source is administered within a body cavity.

208. (Previously Presented) The method according to claim 182 wherein said cell-cycle inhibitor or radioactive source is administered directly into a body tissue.

209. – 219. (Cancelled)

220. (Previously Presented) A method for treating a hyperproliferative disease of the prostate, comprising administering to the prostate a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease of the prostate is treated.

221. (Original) The method according to claim 220 wherein said hyperproliferative disease of the prostate is prostate cancer.

222. (Original) The method according to claim 220 wherein said hyperproliferative disease of the prostate is benign prostatic hypertrophy.

223. – 229. (Cancelled)

230. (Original) The method according to claim 220 wherein said cell-cycle inhibitor comprises at least one taxane, toposiomerase inhibitor, vinca alkaloid, alkalating agent, or estramustine.

231. (Withdrawn) A method for treating a hyperproliferative disease of the anorectum, comprising administering to the anorectum a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease of the anorectum is treated.

232. (Withdrawn) The method according to claim 231 wherein said therapeutic device is administered to the rectal mucosa.

233. – 238. (Cancelled)

239. (Withdrawn) The method according to claim 231 wherein said therapeutic device is injected interstitially.

240. (Withdrawn) The method according to claim 231 wherein said cell-cycle inhibitor comprises at least one taxane, platinum, toposiomerase inhibitor, alkalating agent, mitomycin, or leucovorine.

241. (Withdrawn) A method for treating a hyperproliferative disease of the bladder or urinary tract, comprising administering to the bladder or urinary tract a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

242. (Withdrawn) The method according to claim 241 wherein said hyperproliferative disease is bladder cancer.

243. – 246. (Cancelled)

247. (Withdrawn) The method according to claim 241 wherein said therapeutic device is injected interstitially.

248. (Withdrawn) The method according to claim 241 wherein said cell-cycle inhibitor comprises at least one taxane, ethyleneimine, anthracyclines, antimetabolites, vinca alkaloids, platinum or mitomycin.

249. (Withdrawn) A method for treating a hyperproliferative disease of the eye, comprising administering to the eye a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

250. (Withdrawn) The method according to claim 249 wherein said hyperproliferative disease of the eye is uveal melanoma.

251. (Withdrawn) The method according to claim 249 wherein said hyperproliferative disease of the eye is retinoblastoma.

252. (Withdrawn) The method according to claim 249 wherein said therapeutic device is administered via a surface eye mold.

253. (Withdrawn) The method according to claim 249 wherein said therapeutic device is injected intravitreally, or administered via a shunt.

254. (Cancelled)

255. (Withdrawn) The method according to claim 249 wherein said cell-cycle inhibitor comprises at least one taxane, vinca alkaloid, alkylating agent, anthracycline, platinum, nitrogen mustard or topoisomerase inhibitor.

256. (Withdrawn) A method for treating a hyperproliferative disease of the brain, comprising administering to the brain a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

257. (Withdrawn) The method according to claim 256 wherein said hyperproliferative disease of the brain is a malignant glioma.

258. (Withdrawn) The method according to claim 256 wherein said hyperproliferative disease of the brain is an astrocytoma.

259. – 261. (Cancelled)

262. (Withdrawn) The method according to claim 256 wherein said therapeutic device is injected interstitially.

263. (Withdrawn) The method according to claim 256 wherein said cell cycle inhibitor is administered in a paste, film, or spray.

264. (Withdrawn) The method according to claim 256 wherein said cell-cycle inhibitor comprises at least one taxane, nitrosurea, tetrazine, vinca alkaloid, platinum, topoisomerase inhibitor, antimetabolites, or leucovorin.

265. (Withdrawn) A method for treating a hyperproliferative disease of the breast, comprising administering to the breast a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease of the breast is treated.

266. (Withdrawn) The method according to claim 265 wherein said hyperproliferative disease of the breast is breast cancer.

267. – 270. (Cancelled)

271. (Withdrawn) The method according to claim 265 wherein said therapeutic device is injected interstitially.

272. (Cancelled)

273. (Withdrawn) The method according to claim 265 wherein said cell-cycle inhibitor comprises at least one taxane, anthracycline, alkylating agent, antimetabolite, vinca alkaloid, platinum, nitrogen mustard, gemcitabine, or mitomycin.

274. (Withdrawn) A method for treating a hyperproliferative disease of the esophagus, comprising administering to the esophagus a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

275. (Withdrawn) The method according to claim 274 wherein said hyperproliferative disease of the esophagus is esophageal cancer.

276., 277. (Cancelled)

278. (Withdrawn) The method according to claim 274 wherein said cell-cycle inhibitor comprises at least one taxane, alkylating agent, platinum, or mitomycin.

279. (Withdrawn) A method for treating a hyperproliferative disease of the genital tract, comprising administering to the genital tract a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

280. (Withdrawn) The method according to claim 279 wherein said hyperproliferative disease of the genital tract is penile cancer.

281. (Withdrawn) The method according to claim 279 wherein said hyperproliferative disease of the genital tract is vaginal cancer.

282. – 285. (Cancelled)

286. (Withdrawn) The method according to claim 279 wherein said therapeutic device is administered interstitially.

287. (Cancelled)

288. (Withdrawn) The method according to claim 279 wherein said cell-cycle inhibitor comprises at least one taxane, vinca alkaloid, antimetabolite, platinum or, alkylating agent.

289. (Withdrawn) A method for treating a hyperproliferative disease of the uterus or cervix, comprising administering to the uterus or cervix a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

290. (Withdrawn) The method according to claim 289 wherein said hyperproliferative disease is endometrial cancer.

291. (Withdrawn) The method according to claim 289 wherein said hyperproliferative disease is cervical cancer.

292., 293. (Cancelled)

294. (Withdrawn) The method according to claim 289 wherein said therapeutic device is administered to the surface of the cervix or endometrium.

295. – 297. (Cancelled)

298. (Withdrawn) The method according to claim 289 wherein said therapeutic device is injected interstitially.

299. (Cancelled)

300. (Withdrawn) The method according to claim 289 wherein said cell-cycle inhibitor comprises at least one taxane, platinum, alkylating agent, nitrogen mustard, topoisomerase inhibitor, anthracycline, or estramustine.

301. (Withdrawn) A method for treating a hyperproliferative disease of the liver or bile duct, comprising administering to the liver or bile duct a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

302. (Withdrawn) The method according to claim 301 wherein said hyperproliferative disease is liver cancer.

303. (Withdrawn) The method according to claim 301 wherein said hyperproliferative disease is a biliary tumor.

304. – 308. (Cancelled)

309. (Withdrawn) The method according to claim 301 wherein said therapeutic device is injected interstitially.

310. (Cancelled)

311. (Withdrawn) The method according to claim 301 wherein said cell-cycle inhibitor comprises at least one taxane, anthracyline, platinum, alkylating agent, gemcitabine, mitomycin, or floxuridine.

312. (Withdrawn) A method for treating a hyperproliferative disease of the lung, comprising administering to the lung a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

313. (Withdrawn) The method according to claim 312 wherein said hyperproliferative disease is lung cancer.

314. – 320. (Cancelled)

321. (Withdrawn) The method according to claim 312 wherein said cell-cycle inhibitor comprises at least one taxane, topoisomerase inhibitor, vinca alkaloid, platinum, alkylating agent, anthracycline, nitrogen mustard, antimetabolite, nitrosurea, mitomycin, or gemcitabine.

322. (Withdrawn) A method for treating a hyperproliferative disease of the pancreas, comprising administering to the pancreas a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

323. (Withdrawn) The method according to claim 322 wherein said hyperproliferative disease is pancreatic cancer.

324. – 327. (Cancelled)

328. (Withdrawn) The method according to claim 322 wherein said therapeutic device is administered interstitially.

329. (Cancelled)

330. (Withdrawn) The method according to claim 322 wherein said cell-cycle inhibitor comprises at least one taxane, anthracycline, nitrogen mustard, tetrazine, platinum, antimetabolite, or vinca alkaloid.

331. (Withdrawn) A method for treating soft-tissue sarcomas, comprising administering to a soft-tissue sarcoma a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that sarcoma is treated.

332. – 335. (Cancelled)

336. (Withdrawn) The method according to claim 331 wherein said therapeutic device is administered interstitially.

337. (Cancelled)

338. (Withdrawn) The method according to claim 331 wherein said cell-cycle inhibitor comprises at least one taxane, anthracycline, nitrogen mustard, tetrazine, platinum, antimetabolite, or vinca alkaloid.

339. (Withdrawn) A method for treating a hyperproliferative disease of the skin, comprising administering to the skin a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative is treated.

340. (Withdrawn) The method according to claim 339 wherein said therapeutic device is administered topically, subcutaneously, or intradermally.

341. (Withdrawn) The method according to claim 339 wherein said therapeutic device is administered via a surface mold, or via a transdermal patch.

342. – 345. (Cancelled)

346. (Withdrawn) The method according to claim 339 wherein said cell-cycle inhibitor comprises at least one taxane, alkylating agent, tetrazine, or nitrosurea.

347. (Withdrawn) A method for treating a hyperproliferative disease of the head or neck, comprising administering to the head or neck a therapeutic device comprising a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

348. (Withdrawn) The method according to claim 347 wherein said hyperproliferative disease is a tumor of the tongue, mouth, lip, or, nasopharnyx.

349. – 352. (Cancelled)

353. (Withdrawn) The method according to claim 347 wherein said therapeutic device is administered interstitially.

354. (Original) The method according to claim 347 wherein said cell-cycle inhibitor comprises at least one polypeptide, taxane, antimetabolite, platinum, alkylating agent, nitrogen mustard, anthracycline, or vinca alkaloid.

355. - 357 (Cancelled)

358. (Previously Presented) The device according to claim 1 wherein said cell-cycle inhibitor comprises at least one taxane, anthracycline, toposiomerase inhibitor, vinca alkaloid, alkalating agent, antimetabolite, platinum, nitrogen mustard, gemcitabine, mitomycin, or estramustine.

359. (Previously Presented) The device according to claim 1 or claim 19 wherein said cell-cycle inhibitor comprises paclitaxel, or an analogue or derivative thereof.

360. (Previously Presented) The device according to claim 373 wherein said spacer is positioned between adjacent ones of the plurality of radioactive seeds, the spacers both holding the adjacent seeds spaced apart and holding the plurality of seeds together as part of a continuous thread.

361. (Previously Presented) The method according to claim 362 wherein the spacers are positioned between the seeds and are sized to be received in a catheter for insertion into the tissue.

362. (Previously Presented) The method according to claim 220 wherein the radioactive source comprises a plurality of radioactive seeds.

363. (Previously Presented) The method according to claim 374 wherein said polymer comprises poly (lactic acid).

364. (Previously Presented) The method according to claim 220 wherein said cell-cycle inhibitor comprises paclitaxel, or an analogue or derivative thereof.

365. (Previously Presented) The method according to claim 220 wherein said radioactive source is selected from the group consisting of I^{125}, Pd^{103}, Ir^{192}, Co^{60}, Cs^{137}, and Ru^{106}.

366. (Previously Presented) The method according to claim 362 wherein said spacer is positioned between adjacent ones of the plurality of radioactive seeds, the spacers both holding the adjacent seeds spaced apart while in the tissue and holding the plurality of seeds together as part of a continuous thread while being positioned in the tissue.

367. (Previously Presented) The method according to claim 368 wherein the spacers are positioned between the seeds and are sized to be received in a catheter for insertion into the tissue.

368. (Previously Presented) The method according to claim 265 wherein the radioactive source comprises a plurality of radioactive seeds.

369. (Previously Presented) The method according to claim 375 wherein said polymer comprises poly (lactic acid).

370. (Previously Presented) The method according to claim 265 wherein said radioactive source is selected from the group consisting of I^{125}, Pd^{103}, Ir^{192}, Co^{60}, Cs^{137}, and Ru^{106}.

371. (Previously Presented) The method according to claim 265 wherein said cell-cycle inhibitor comprises paclitaxel, or an analogue or derivative thereof.

372. (Previously Presented) The method according to claim 368 wherein said spacer is positioned between adjacent ones of the plurality of radioactive seeds, the spacers both holding the adjacent seeds spaced apart while in the tissue and holding the plurality of seeds together as part of a continuous thread while being positioned in the tissue.

373. (Previously Presented) The device according to claim 1 wherein the radioactive source comprises a plurality of radioactive seeds.

374. (Previously Presented) The method according to claim 220 wherein the material selected for the spacer is a polymer.

375. (Previously Presented) The method according to claim 265 wherein the material selected for the spacer is a polymer.